REMARKS/ARGUMENTS

Status of the Claims

Claims 1-33 were originally pending in this application. Claims 1-29 and 31-33 have been rejected. Claim 30 is objected to. Claim 1 has been amended. Claims 4 and 5 have been canceled. An objection was set forth in the Office Action with respect to the drawings. The specification has been amended in light of the objection to the drawings. No new matter has been entered by way of amendment. Applicant asks that all claims be examined and allowed.

Drawing Objection

The Examiner has objected to the drawings as being not in accordance with 37 CFR 1.84. The Applicant has amended the specification to add reference characters that were identified in Figures 4A and 5 but not mentioned in the description. No new matter has been entered. The Applicant requests withdrawal of the objection.

The Rejections of Claims 1-3, 6-7, 11-19, 23, 26, 29, and 31 Under 35 U.S.C. §102(b) Should be Withdrawn

Claims 1-3, 6-7, 11-19, 23, 26, 29, and 31 were rejected under 35 U.S.C. 102(b), as being anticipated by USP 6,419,692 to Yang *et al.*

To establish a case of *prima facie* anticipation, the single reference cited by the Examiner must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons or ordinary skill in the field of the invention. (Crown

Operations Int, Ltd. V. Solutia Inc., 289 F.3d 1367, 1375, 62 USPQ2d 1917, 1921 (Fed Cir. 1984)). For the following reasons, the Applicants believe that the Examiner has not established a case of *prima facie* anticipation because Yang *et al.* does not describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art.

Claims 1-3, 6-7, 11-17

Claim 1 of the present invention describes a drug eluting brachytherapy device, comprising: an insertion member having a proximal portion, a distal portion, and at least one lumen extending therethrough; an expandable surface member mated to the distal portion of the insertion member and defining a spatial volume therein; and a treatment agent releasably mated with the expandable surface member; wherein at least a portion of the treatment agent is delivered to adjacent tissue when the brachytherapy device is positioned within a tissue cavity.

The Examiner states that Yang *et al.* teaches a drug eluting brachytherapy device. The Applicants respectfully disagree that Yang *et al.* teaches a brachytherapy device. The term brachytherapy as described in the Applicant's specification refers to "...radiation therapy delivered by a source of therapeutic rays inserted into the body at or near a tumor or other proliferative tissue disease site." (column 1; paragraph 0002). Although the Applicants believe that Claim 1 sets out and distinguishes the device of the present invention as a brachytherapy device, in order to expedite prosecution, the Applicants have amended claim 1 to include the limitations of claim 4 and 5 to clearly identify the device of the present invention as a drug eluting brachytherapy apparatus.

Since Yang *et al.* does not teach or suggest the use of a drug eluting brachytherapy device (i.e., a device configured to receive a radiation source to enable a three-dimensional isodose profile that is substantially similar in shape to said expandable surface member), Yang *et al.* cannot anticipate Claim 1 or Claims 2-3, 6-7, 11-17 which depend therefrom.

Claims 18-19, 23

Claim 18 of the present invention describes a drug eluting tissue positioning device for positioning target tissue surrounding a resected tissue cavity so that the target tissue can receive a measured radiation dose, comprising: a catheter body member having a proximal portion and a distal portion; an expandable surface member, the expandable surface member defining a spatial volume; and a treatment agent releasably mated with the outer surface of the expandable surface member; wherein at least a portion of the treatment agent is delivered to tissue surrounding the resected tissue cavity when the device is positioned within the resected tissue cavity.

The Examiner states that Yang *et al.* teaches in part "...a treatment agent (30) is delivered to adjacent tissue (54, 56) when the brachytherapy device is positioned within a tissue cavity (as described in lines 2-10 of column 3)." (Office Action page 4; section d). The Applicants respectfully disagree that Yang *et al.* teaches a brachytherapy device for positioning target tissue within a tissue cavity for the following reasons.

First, as mentioned previously, Yang *et al.* does not teach or suggest a brachytherapy device and a brachytherapy device is not a limitation found anywhere in Claim 18. Claim 18 describes a drug eluting tissue positioning device for positioning target tissue surrounding a resected tissue cavity. Nowhere in Yang *et al.* is there any mention of a tissue positioning

device. Yang *et al.* describes an endovascular stent for the delivery of drugs or other therapeutics. A stent is not a tissue positioning device. A tissue positioning device holds tissues in a particular orientation in order to receive a therapeutic ray from a radiation source (either internal or external). Since Yang *et al.* does not teach or suggest a tissue positioning device, Yang *et al.* cannot anticipate Claim 18 or any claims that depend therefrom.

Second, Yang *et al.* does not teach or suggest a device for positioning target tissue surrounding a resected tissue cavity. Yang *et al.* describes an endovascular stent for the delivery of drugs or other therapeutics within a body lumen (i.e., within the vascular system). A body lumen is not a resected tissue cavity. Medical devices that are configured to fit into a body lumen are of different shape and have different functions than those medical devices that are configured to fit into a resected tissue cavity. Since Yang *et al.* does not teach or suggest a device for positioning target tissue surrounding a resected tissue cavity, Yang *et al.* cannot anticipate Claim 18 or any claims that depend therefrom.

Since Yang *et al.* does not teach or suggest a device for positioning target tissue surrounding a resected tissue cavity, Yang *et al.* cannot anticipate Claim 18 or Claims 19 and 23 which depend therefrom.

Separately, Claim 19 of the present invention describes a device wherein an expandable surface member is constructed of a material permeable to a treatment agent. The Examiner argues that "...the expandable surface member (62) is constructed of a material permeable to the treatment agent (as seen as layer 30 in Figure 5)."(Office Action page 5; section l). The Applicants respectfully disagree that layer 30 as shown in Figure 5 of Yang *et al* is constructed of a material that is permeable to a treatment agent (i.e., a liquid). Nowhere in Yang *et al* is there

any teaching or suggestion that the stent or balloon catheter described in Yang *et al.* has a permeable membrane. Since Yang *et al.* does not teach or suggest a device with a permeable membrane, Yang *et al.* cannot anticipate Claim 19.

Claims 26, 29 and 31

Claim 26 of the present invention describes a method of delivering a treatment material, comprising: providing a drug eluting brachytherapy device having a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with the expandable surface member; positioning the brachytherapy device within a tissue cavity; and delivering the treatment agent to tissue surrounding the tissue cavity.

In the present Office Action, the Examiner has not pointed to any teaching in Yang *et al.* which describes a method of positioning a brachytherapy device within a tissue cavity and delivering a treatment agent to tissue surrounding the tissue cavity where the catheter is comprised of a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with the expandable surface member. As mentioned previously, Yang *et al.* does not teach or suggest a brachytherapy device nor does Yang *et al.* teach or suggest positioning a brachytherapy device within a tissue cavity and delivering a treatment agent to tissue surrounding the tissue cavity.

Since Yang *et al.* does not teach or suggest a method of positioning a brachytherapy device within a tissue cavity and delivering a treatment agent to tissue surrounding the tissue

cavity where the catheter is comprised of a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with the expandable surface member, Yang *et al.* cannot anticipate Claim 26 or Claims 29 and 31 which depend therefrom.

For all of the reasons stated above, withdrawal of the objections under 35 U.S.C. 102(b), is respectfully requested.

The Rejections of Claims 1-9, 11-13, 16, 18-22, 24-26, and 31-33 Under 35 U.S.C. §102(b) Should be Withdrawn

Claims 1-9, 11-13, 16, 18-22, 24-26, and 31-33 were rejected under 35 U.S.C. 102(b), as being anticipated by USP 6,458,069 to Tam *et al.*

To establish a case of *prima facie* anticipation, the single reference cited by the Examiner must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons or ordinary skill in the field of the invention. (Crown Operations Int, Ltd. V. Solutia Inc., 289 F.3d 1367, 1375, 62 USPQ2d 1917, 1921 (Fed Cir. 1984)). For the following reasons, the Applicants believe that the Examiner has not established a case of *prima facie* anticipation because Tam *et al.* does not describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art.

Claims 1-9, 11-13, 11-16

Claim 1 of the present invention describes a drug eluting brachytherapy device, comprising: an insertion member having a proximal portion, a distal portion, and at least one lumen extending therethrough; an expandable surface member mated to the distal portion of the insertion member and defining a spatial volume therein; and a treatment agent releasably mated with the expandable surface member; wherein at least a portion of the treatment agent is delivered to adjacent tissue when the brachytherapy device is positioned within a tissue cavity.

The Examiner states that Tam *et al.* teaches a drug eluting brachytherapy device that may be positioned within a tissue cavity. The Applicant respectfully disagrees that Tam *et al.* teaches or suggests the use of the radiation delivery balloon in a tissue cavity. Tam *et al.* teaches a sealed radiation source used to deliver a radioactive dose to a site in a body lumen (see abstract). Although the Applicants believe that Claim 1 sets out and distinguishes the device of the present invention as a brachytherapy device that is positioned in a tissue cavity, in order to expedite prosecution, the Applicants have amended claim 1 to include the limitations of claim 4 and 5 to specifically call out that the described radiation source of the present invention enables a three-dimensional isodose profile that is substantially similar in shape to the expandable surface member of the drug eluting brachytherapy device.

Since Tam *et al.* does not teach or suggest the use of a drug eluting brachytherapy device configured to receive a radiation source to enable a three-dimensional isodose profile that is substantially similar in shape to the expandable surface member of the brachytherapy device, Tam *et al.* cannot anticipate Claim 1 or Claims 2-9, 11-13, 11-16 which depend therefrom.

Claims 18-22, 24-25

Claim 18 of the present invention describes a drug eluting tissue positioning device for positioning target tissue surrounding a resected tissue cavity so that the target tissue can receive a measured radiation dose, comprising: a catheter body member having a proximal portion and a distal portion; an expandable surface member, the expandable surface member defining a spatial volume; and a treatment agent releasably mated with the outer surface of the expandable surface member; wherein at least a portion of the treatment agent is delivered to tissue surrounding the resected tissue cavity when the device is positioned within the resected tissue cavity.

The Examiner states that Tam *et al.* teaches in part "...a treatment agent is delivered to adjacent tissue when the brachytherapy device is positioned within a tissue cavity (as described in lines 28-38 of column 19 and in the abstract)." (Office Action page 6; section f). The Applicants respectfully disagree that Tam *et al.* teaches a brachytherapy device for positioning target tissue within a tissue cavity for the following reason.

Tam *et al.* does not teach or suggest a device for positioning target tissue surrounding a resected tissue cavity. Tam *et al.* describes a sealed radiation source which may be used to deliver a radioactive dose to a site in a body lumen (i.e., within the vascular system). A body lumen is not a resected tissue cavity. Medical devices that are configured to fit into a body lumen are of different shape and have a different function than brachytherapy devices that are configured to fit into a resected tissue cavity. Since Tam *et al.* does not teach or suggest a device for positioning target tissue surrounding a resected tissue cavity, Tam *et al.* cannot anticipate Claim 18 or any claims that depend therefrom.

Since Tam *et al.* does not teach or suggest a device for positioning target tissue surrounding a resected tissue cavity, Tam *et al.* cannot anticipate Claim 18 or Claims 19-22, and 24-25 which depend therefrom.

Separately, Claims 19-22 of the present invention teach the use of a second treatment agent which is capable of permeating through the walls of the expandable surface member (i.e., a liquid as required by the fluid delivery path of Claim 21). Tam *et al.* does not teach or suggest a device with a permeable expandable membrane or a second treatment agent. The Examiner points to Figures 4-7 and 9-9A as teaching different treatment agents however, Figures 4-7 and 9-9A only show different layers of bonding materials which make up the composition of the radiation balloon. There is no mention in Tam *et al.* of additional treatment agents. Since Tam *et al.* does not teach or suggest a device with a permeable membrane or different treatment agents, Tam *et al.* cannot anticipate Claims 19-22.

Claims 26, 31-33

Claim 26 of the present invention describes a method of delivering a treatment material, comprising: providing a drug eluting brachytherapy device having a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with the expandable surface member; positioning the brachytherapy device within a tissue cavity; and delivering the treatment agent to tissue surrounding the tissue cavity.

In the present Office Action, the Examiner has not pointed to any teaching in Tam *et al.* which describes a method of positioning a brachytherapy device within a tissue cavity and

delivering a treatment agent to tissue surrounding the tissue cavity where the catheter is comprised of a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with the expandable surface member. As mentioned previously, Tam *et al.* does not teach or suggest positioning a brachytherapy device within a tissue cavity and delivering a treatment agent to tissue surrounding the tissue cavity.

Since Tam *et al.* does not teach or suggest of positioning a brachytherapy device within a tissue cavity and delivering a treatment agent to tissue surrounding the tissue cavity where the catheter is comprised of a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with the expandable surface member, Tam *et al.* cannot anticipate Claim 26 or Claims 31-33 which depend therefrom.

For all of the reasons stated above, withdrawal of the objections under 35 U.S.C. 102(b), is respectfully requested.

The Rejections of Claims 1-3, 6-7, 13-14, 16-18, 26, 28 and 31 Under 35 U.S.C. §102(b) Should be Withdrawn

Claims 1-3, 6-7, 13-14, 16-18, 26, 28 and 31 were rejected under 35 U.S.C. 102(b), as being anticipated by USP 6,409,716 to Sahatjian *et al.*

To establish a case of *prima facie* anticipation, the single reference cited by the Examiner must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its

existence was recognized by persons or ordinary skill in the field of the invention. (Crown Operations Int, Ltd. V. Solutia Inc., 289 F.3d 1367, 1375, 62 USPQ2d 1917, 1921 (Fed Cir. 1984)). For the following reasons, the Applicants believe that the Examiner has not established a case of *prima facie* anticipation because Sahatjian *et al.* does not describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art.

Claims 1-3, 6-7, 13-14, 16-17

Claim 1 of the present invention describes a drug eluting brachytherapy device, comprising: an insertion member having a proximal portion, a distal portion, and at least one lumen extending therethrough; an expandable surface member mated to the distal portion of the insertion member and defining a spatial volume therein; and a treatment agent releasably mated with the expandable surface member; wherein at least a portion of the treatment agent is delivered to adjacent tissue when the brachytherapy device is positioned within a tissue cavity.

The Examiner states that Sahatjian *et al.* teaches a drug eluting brachytherapy device. The Applicants respectfully disagree that Sahatjian *et al.* teaches a brachytherapy device. Sahatjian *et al.* teaches a drug delivery device not a brachytherapy device. The term brachytherapy as described in the Applicant's specification refers to "...radiation therapy delivered by a source of therapeutic rays inserted into the body at or near a tumor or other proliferative tissue disease site." (column 1; paragraph 0002). Although the Applicants believe that Claim 1 sets out and distinguishes the device of the present invention as a brachytherapy device, in order to expedite prosecution, the Applicants have amended claim 1 to include the

limitations of claim 4 and 5 to clearly identify the device of the present invention as a drug eluting brachytherapy apparatus.

Since Sahatjian *et al.* does not teach or suggest the use of a drug eluting brachytherapy device (i.e., a device configured to receive a radiation source to enable a three-dimensional isodose profile that is substantially similar in shape to said expandable surface member), Sahatjian *et al.* cannot anticipate Claim 1 or Claims 2-3, 6-7, 13-14, and 16-17 which depend therefrom.

Claims 18 and 26

Claim 18 of the present invention describes a drug eluting tissue positioning device for positioning target tissue surrounding a resected tissue cavity so that the target tissue can receive a measured radiation dose, comprising: a catheter body member having a proximal portion and a distal portion; an expandable surface member, the expandable surface member defining a spatial volume; and a treatment agent releasably mated with the outer surface of the expandable surface member; wherein at least a portion of the treatment agent is delivered to tissue surrounding the resected tissue cavity when the device is positioned within the resected tissue cavity.

The Examiner states that Sahatjian *et al.* teaches in part "...delivering the treatment agent (8, 44) to tissue surrounding the tissue cavity (as described in lines 52-67 of column 1)." (Office Action page 8; section e). The Applicants respectfully disagree that Sahatjian *et al.* teaches a brachytherapy device for positioning target tissue within a tissue cavity for the following reasons.

Sahatjian *et al.* does not teach or suggest a device for positioning target tissue surrounding a resected tissue cavity. Sahatjian *et al.* describes a balloon catheter for the delivery of drugs or other therapeutics within a body lumen (i.e., within the vascular system). A body lumen is not a resected tissue cavity. Medical devices that are configured to fit into a body lumen are of different shape and have different functions than those medical devices that are configured to fit into a resected tissue cavity. Since Sahatjian *et al.* does not teach or suggest a device for positioning target tissue surrounding a resected tissue cavity, Sahatjian *et al.* cannot anticipate Claim 18 or any claims that depend therefrom.

Since Sahatjian *et al.* does not teach or suggest a device for positioning target tissue surrounding a resected tissue cavity, Sahatjian *et al.* cannot anticipate Claim 18 or Claim 26 which depends therefrom.

Claims 26, 29 and 31

Claim 26 of the present invention describes a method of delivering a treatment material, comprising: providing a drug eluting brachytherapy device having a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with the expandable surface member; positioning the brachytherapy device within a tissue cavity; and delivering the treatment agent to tissue surrounding the tissue cavity.

In the present Office Action, the Examiner has not pointed to any teaching in Sahatjian *et al.* which describes a method of positioning a brachytherapy device within a tissue cavity and

delivering a treatment agent to tissue surrounding the tissue cavity where the catheter is comprised of a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with the expandable surface member. As mentioned previously, Sahatjian *et al.* does not teach or suggest a brachytherapy device nor does Sahatjian *et al.* teach or suggest positioning a brachytherapy device within a tissue cavity and delivering a treatment agent to tissue surrounding the tissue cavity.

Since Sahatjian *et al.* does not teach or suggest of positioning a brachytherapy device within a tissue cavity and delivering a treatment agent to tissue surrounding the tissue cavity where the catheter is comprised of a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with the expandable surface member, Sahatjian *et al.* cannot anticipate Claim 26 or Claims 29 and 31 which depend therefrom.

For all of the reasons stated above, withdrawal of the objections under 35 U.S.C. 102(b), is respectfully requested.

The Rejections of Claims 1-3, 6-7, 10, 13, 16, 18-21, 26, 31, 32, and 33 Under 35 U.S.C. §102(b) Should be Withdrawn

Claims 1-3, 6-7, 10, 13, 16, 18-21, 26, 31, 32, and 33 were rejected under 35 U.S.C. 102(b), as being anticipated by USP 5,286,254 to Shapland *et al.*

To establish a case of *prima facie* anticipation, the single reference cited by the Examiner must describe and enable the claimed invention, including all claim limitations, with sufficient

clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons or ordinary skill in the field of the invention. (Crown Operations Int, Ltd. V. Solutia Inc., 289 F.3d 1367, 1375, 62 USPQ2d 1917, 1921 (Fed Cir. 1984)). For the following reasons, the Applicants believe that the Examiner has not established a case of *prima facie* anticipation because Shapland *et al.* does not describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art.

Claims 1-3, 6-7, 10, 13, 16

Claim 1 of the present invention describes a drug eluting brachytherapy device, comprising: an insertion member having a proximal portion, a distal portion, and at least one lumen extending therethrough; an expandable surface member mated to the distal portion of the insertion member and defining a spatial volume therein; and a treatment agent releasably mated with the expandable surface member; wherein at least a portion of the treatment agent is delivered to adjacent tissue when the brachytherapy device is positioned within a tissue cavity.

The Examiner states that Shapland *et al.* teaches a drug eluting brachytherapy device. The Applicants respectfully disagree that Shapland *et al.* teaches a brachytherapy device. The term brachytherapy as described in the Applicant's specification refers to "...radiation therapy delivered by a source of therapeutic rays inserted into the body at or near a tumor or other proliferative tissue disease site." (column 1; paragraph 0002). Although the Applicants believe that Claim 1 sets out and distinguishes the device of the present invention as a brachytherapy device, in order to expedite prosecution, the Applicants have amended claim 1 to include the

limitations of claim 4 and 5 to clearly identify the device of the present invention as a drug eluting brachytherapy apparatus.

Since Shapland *et al.* does not teach or suggest the use of a brachytherapy device (i.e., a device configured to receive a radiation source to enable a three-dimensional isodose profile that is substantially similar in shape to said expandable surface member), Shapland *et al.* cannot anticipate Claim 1 or Claims 2-3, 6-7, 10, 13, and 16 which depend therefrom.

Claims 18- 21

Claim 18 of the present invention describes a drug eluting tissue positioning device for positioning target tissue surrounding a resected tissue cavity so that the target tissue can receive a measured radiation dose, comprising: a catheter body member having a proximal portion and a distal portion; an expandable surface member, the expandable surface member defining a spatial volume; and a treatment agent releasably mated with the outer surface of the expandable surface member; wherein at least a portion of the treatment agent is delivered to tissue surrounding the resected tissue cavity when the device is positioned within the resected tissue cavity.

The Examiner states that Shapland *et al.* teaches in part "...treatment agent is delivered to adjacent tissue when the brachytherapy device is positioned within a tissue cavity (as described in lines 5-10 of column 3)." (Office Action page 10; section c). The Applicants respectfully disagree that Shapland *et al.* teaches a brachytherapy device for positioning target tissue within a tissue cavity for the following reasons.

Shapland *et al.* does not teach or suggest a device for positioning target tissue surrounding a resected tissue cavity. Shapland *et al.* describes a balloon catheter for the delivery

of drugs or other therapeutics within a body lumen (i.e., within the vascular system). A body lumen is not a resected tissue cavity. Medical devices that are configured to fit into a body lumen are of different shape and have different functions than those medical devices that are configured to fit into a resected tissue cavity. Since Shapland *et al.* does not teach or suggest a device for positioning target tissue surrounding a resected tissue cavity, Shapland *et al.* cannot anticipate Claim 18 or any claims that depend therefrom.

Since Shapland *et al.* does not teach or suggest a device for positioning target tissue surrounding a resected tissue cavity, Shapland *et al.* cannot anticipate Claim 18 or Claims 19-21 which depends therefrom.

Claims 26, 31, 32 and 33

Claim 26 of the present invention describes a method of delivering a treatment material, comprising: providing a drug eluting brachytherapy device having a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with the expandable surface member; positioning the brachytherapy device within a tissue cavity; and delivering the treatment agent to tissue surrounding the tissue cavity.

In the present Office Action, the Examiner has not pointed to any teaching in Shapland *et al.* which describes a method of positioning a brachytherapy device within a tissue cavity and delivering a treatment agent to tissue surrounding the tissue cavity where the catheter is comprised of a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated

with the expandable surface member. As mentioned previously, Shapland *et al.* does not teach or suggest a brachytherapy device nor does Shapland *et al.* teach or suggest positioning a brachytherapy device within a tissue cavity and delivering a treatment agent to tissue surrounding the tissue cavity.

Since Shapland *et al.* does not teach or suggest of positioning a brachytherapy device within a tissue cavity and delivering a treatment agent to tissue surrounding the tissue cavity where the catheter is comprised of a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with the expandable surface member, Shapland *et al.* cannot anticipate Claim 26 or Claims 31, 32 and 33 which depend therefrom.

For all of the reasons stated above, withdrawal of the objections under 35 U.S.C. 102(b), is respectfully requested.

The Rejections of Claim 27 Under 35 U.S.C. §103(a) Should be Withdrawn

Claim 27 was rejected under 35 U.S.C. 103(a), as being unpatentable over USP 6,458,069 to Tam *et al.* in view of USP 5,422,926 to Smith *et al.*

The Examiner has argued that the method of delivering a treatment agent to areas either naturally occurring or surgically created that may benefit from the treatment agent as taught by Tam *et al.* in combination with the method of using a catheter to deliver a treatment agent to a tissue cavity created from a lumpectomy procedure as taught by Smith *et al.*, anticipates the

Applicant's present invention of a method of delivering a treatment material, comprising: providing a drug eluting brachytherapy device having a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with the expandable surface member; positioning the brachytherapy device within a tissue cavity; and delivering the treatment agent to tissue surrounding the tissue cavity wherein the tissue cavity is a resected tissue cavity created during a lumpectomy procedure as recited in claim 27. The Appellant respectfully disagrees that the Examiner has established a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied references, or in the form of generally available knowledge, that one having ordinary skill in the art would have been motivated to make the claimed invention. See, *e.g.*, *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); and *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985).

A new combination of elements can be patented "whether it be composed of elements all new, partly new or all old." *Rosmount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546, 221 USPQ 1, 7 (CAFC 1984). The Court of Appeals for the Federal Circuit has forcefully stated that a claim rejection must provide a specific motivation in the art for combining elements from cited art in order to establish obviousness of a new combination.

> "[C]ase law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. ... Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence

> of hindsight. ... [Evidence of a suggestion, teaching, or motivation to combine] must be clear and particular. ... Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.' ... [A] reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the [cited] references teach or suggest their combination ... to yield the claimed invention," and a conclusion of obviousness based on such an analysis "as a matter of law, cannot stand." *In re Dembiczak*, 175 F.3d 994, 999, 1000, 50 USPQ2d 1614, 1617, 1618 (Fed. Cir. 1999), emphasis added.

Dembiczak involved patent claims to "a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern." *Dembiczak*, 996, 1616. The prior art cited by the Board included: a book describing how to teach children to make a "Crepe Paper Jack-O-Lantern;" a book describing a method of making a "paper bag pumpkin" by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint; a U.S. Patent describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material; design patents issued to Dembiczak; and prior art "conventional" plastic lawn or trash bags. The Federal Circuit held that the claimed pumpkin-style trash bag was not obvious because there was no clear, particular motivation to combine the cited references.

This holding of *Dembiczak* that evidence of motivation to combine must be clear and particular to establish obviousness has been emphasized over and over again by the Federal Circuit since *Dembiczak* was decided. It was strongly reemphasized in *Ruiz v. A.B. Chance Co.*, 57 USPQ2d 1161 (Fed. Cir. 2000):

> In order to prevent a hindsight-based obviousness analysis, we have clearly established that the relevant inquiry for determining the scope and content of the prior art is whether there is a reason, suggestion, or motivation in the prior art or elsewhere that would have led one of ordinary skill in the art to combine the references. See, e.g., In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459

> (Fed. Cir. 1998) ("[T]he Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious."); In re Dembiczak, 175 F.3d at 999, 50 USPQ2d at 1617 ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."). "Determining whether there is a suggestion or motivation to modify a prior art reference is one aspect of determining the scope and content of the prior art, a fact question subsidiary to the ultimate conclusion of obviousness." Sibia Neurosciences, Inc. v. Cadus Pharma. Corp., 225 F.3d 1349, 1356, 55 USPQ2d 1927, 1931 (Fed. Cir. 2000); Tec Air, Inc. v. Denso Mfg., Inc., 192 F.3d 1353, 1359, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) (stating that the factual underpinnings of obviousness include whether a reference provides a motivation to combine its teachings with those of another reference).
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> ... there is "a general rule that combination claims can consist of combinations of old elements as well as new elements," Clearstream Wastewater Sys. v. Hydro-Action, Inc., 206 F.3d 1440, 1446, 54 USPQ2d 1185, 1189-90 (Fed. Cir. 2000), "[t]he notion . . . that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, § 103." Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1575, 1 USPQ2d 1593, 1603 (Fed. Cir. 1987); Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997) ("It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements."). *Ruiz* at 1167

Applying this standard to the references cited by the Examiner, it is clear that the Examiner has failed to meet the burden of providing evidence of a motivating force sufficient to impel a person of ordinary skill in the art to combine the teachings in the applied references in the proposed manner to arrive at the claimed invention. The motivation cited in the Final Office Action for the proposed combination is as follows:

> "It would have been obvious to one of ordinary skill in the art at the time of the invention to use a method similar to the of Tam et al. to treat tissue cavity created from a lumpectomy procedure similar to the method of Smith et al. in

order to treat the surgical site and reduce the risk of reoccurrence of the removed tumor." (page 12, section 18).

This statement does not provide the clear, particular suggestion in the art for making the specific claimed combination as is required. The Examiner has failed to meet the burden of providing evidence of a motivating force sufficient to impel a person of ordinary skill in the art to use a method of delivering a treatment material, comprising: providing a drug eluting brachytherapy device having a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with the expandable surface member; positioning the brachytherapy device within a tissue cavity; and delivering the treatment agent to tissue surrounding the tissue cavity wherein the tissue cavity is a resected tissue cavity created during a lumpectomy procedure as recited in claim 27.

The Examiner argues that Tam *et al.* teaches a method of delivering a treatment material comprising providing a drug eluting brachytherapy device having a catheter body member, an expandable surface member and a treatment agent releasably mated with the expandable surface member wherein the brachytherapy device is positioned within a tissue cavity and the treatment agent is delivered to the tissue surrounding the cavity. The Applicants respectfully disagree with the Examiner's characterization of the teaching of Tam *et al.*

In the present Office Action, the Examiner has not pointed to any teaching in Tam *et al.* of the treatment of a tissue cavity. The Examiner points to column 20; lines 14-24 of Tam *et al.* as teaching that the treatment may be delivered to areas either naturally occurring or surgically related. The suggestion that Tam *et al.* teaches the delivery of a treatment agent to a tissue cavity

is misplaced. A reading of Tam *et al.* at column 20 lines 14-24 only describes "...surgically created lumens such as, for example, transjugular intrahepatic portosystemic shunts..." (column 20; lines 21-23). There is no mention of surgically created cavities at all. As mentioned previously, lumens are not cavities.

It would not have been obvious to one of ordinary skill in the art to modify the method of Smith *et al.* because no motivation existed to use the x-ray source of Smith *et al.* in a body cavity and such a modification would have been contrary to the common knowledge of the ordinary artisan. Smith *et al.* describes an x-ray source for external treatment of tissue, not the internal use of a radiation source for brachytherapy.

The obviousness rejection is based on hindsight from these disparate references to provide random elements of the claims. There is no clear, particular motivation in the references to reach the claimed invention.

Thus, a *prima facie* case of obviousness has not been established because the Examiner has not presented evidence that one having ordinary skill in the art would have been motivated to combine Tam *et al.* with the teaching of Smith *et al.*, to make the claimed invention.

Withdrawal of the objections under 35 U.S.C. 103(a), is respectfully requested.

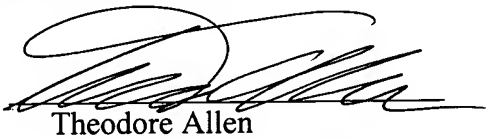
CONCLUSION

It is believed that no extension is required for this submission. If any additional fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 502855, accordingly. If any questions or issues remain, the resolution of

which the Examiner feels would be advanced by a conference with Applicant, the Examiner is invited to contact Applicant's attorney at the number noted below.

Respectfully submitted,

Customer No, 0000 38732

By: 

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